IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA

BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.; BOEHRINGER INGELHEIM INTERNATIONAL GmbH; BOEHRINGER INGELHEIM CORPORATION; BOEHRINGER INGELHEIM PHARMA GmbH & CO. KG,

Plaintiffs,

v. **CIVIL ACTION NO. 1:20CV19**
C/W 1:20CV90
(Judge Keeley)

MYLAN PHARMACEUTICALS, INC.; MYLAN, INC.; MYLAN LABORATORIES, LIMITED,

Defendants.

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BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.; BOEHRINGER INGELHEIM INTERNATIONAL GmbH; BOEHRINGER INGELHEIM CORPORATION; BOEHRINGER INGELHEIM PHARMA GmbH & CO. KG,

Plaintiffs,

CIVIL ACTION NO. 5:20CV23
v. **(Judge Keeley)**

AUROBINDO PHARMA LTD.,[1]

Defendant.

MEMORANDUM OPINION AND ORDER
ADOPTING PLAINTIFFS' PROPOSED CLAIM CONSTRUCTION

This patent infringement case involves three United States Patents issued to Boehringer Ingelheim Pharmaceuticals, Inc.

[1] Boehringer also alleged that Aurobindo Pharm. Ltd. infringed U.S. Patent No. 9,486,526, but that matter, Case No. 5:20CV23, was dismissed on July 2, 2021, pursuant to a consent judgment (Dkt. No. 153).

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("Boehringer") (Dkt. No. 1).[2] The proposed claim construction at issue pertains to U.S. Patent No. 9,486,526 (the "'526 patent"), entitled "Treatment for Diabetes in Patients Inappropriate for Metformin Therapy." (Dkt. Nos. 1 at 7; 71 at n.1). The pharmaceutical composition and methods described in this patent are used to produce TRADJENTA®, a prescription drug which targets the treatment of diabetes in patients for whom treatment with metformin may be inappropriate (Dkt. No. 72 at 7).

The parties dispute the construction of two claim terms: 1) ". . . wherein said DPP-4 inhibitor is used for said patient in the same dose as for a patient with normal renal function" (the "DPP-4 claim term"); and 2) ". . . wherein the patient may be on insulin and/or sulfonylurea background medication" (the "'may' claim term"). For the reasons discussed below, the Court adopts the plaintiffs' proposed construction of these terms.

I. BACKGROUND

In these consolidated, first-filed Hatch-Waxman lawsuits, Boehringer alleges that the defendants, Mylan Pharmaceuticals Inc., Mylan Inc., and Mylan Laboratories Limited (collectively, "Mylan"),

[2] All docket references are to Case No. 1:20CV19 unless noted otherwise.

have infringed the '526 patent, U.S. Patent No. 9,415,016 ("the '016 patent"), and U.S. Patent No. 10,022,379 ("the '379 patent") (Dkt. No. 1; Case No. 1:20CV90, Dkt. No. 1).[3] The '526 patent is a continuation of U.S. Patent No. 8,853,156 (Dkt. No. 72-10 at 2). U.S. Patent No. 10,034,877 ("the '877 patent") is a continuation of the '526 patent. Id.

Relative to the '526 patent, Boehringer holds New Drug Application No. 201280 and sells and markets "linagliptin, for oral use, in 5 mg dosage, which is sold under the trade name TRADJENTA®." (Dkt. No. 1 at 7). After receiving notice and certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that Mylan had filed Abbreviated New Drug Application No. 208431, seeking FDA approval to manufacture and sell a generic version of TRADJENTA®, Boehringer sued Mylan for infringement. Id. at 3, 7-9.

Following a full briefing by the parties outlining their respective positions as to how the Court should construe the disputed claim terms in the '526 patent, (Dkt. Nos. 72, 73), the

[3] The '016 patent and the '379 patent concern linagliptin and metformin hydrochloride in 2.5 mg/500 mg, 2.5 mg/850 mg, and 2.5 mg/1000 mg doses, sold under the trade name JENTADUETO® (Case No. 1:20CV90, Dkt. No. 1 at 6-7). Although this matter has been consolidated with Case No. 1:20CV19, these patents are not at issue in this claim construction dispute.

Court held a Markman hearing on February 10, 2021, (Dkt. No. 127). The matter is now ripe for decision.

II. LEGAL STANDARDS

The construction of patent claims is a matter of law governed by federal statutes and the decisions of the Supreme Court of the United States and the United States Court of Appeals for the Federal Circuit. See Markman v. Westview Instruments, Inc., 52 F.3d 967, 979 (Fed. Cir. 1995). When interpreting the meaning of a claim, a court may consider the context, the specification, and the prosecution histories as intrinsic evidence. Id. (quoting Unique Concepts, Inc. v. Brown, 939 F.2d 1558, 1561 (Fed. Cir. 1991)). "It is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude." Phillips v. AWH Corp., 415 F.3d 1303, 1312 (Fed. Cir. 2005) (internal quotation marks omitted). The description of an invention in the claims, therefore, limits the scope of the invention. Id. "[T]here is no magic formula or catechism for conducting claim construction." Id. at 1324. Instead, the Court is free to attach the appropriate weight to appropriate sources "in light of the statutes and policies that inform patent law." Id.

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"[T]he words of a claim are generally given their ordinary and customary meaning [which is] the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application." Id. at 1312-13 (internal citations and quotation marks omitted). "[T]he ordinary meaning of a claim term is its meaning to the ordinary artisan after reading the entire patent." Id. at 1321 (internal quotation marks omitted).

When construing patent claims, then, a court must consider the context of the entire patent, including both asserted and unasserted claims. Id. at 1314. Because a patent will ordinarily use patent terms consistently, "the usage of a term in one claim can often illuminate the meaning of the same term in other claims." Id. Accordingly, "[d]ifferences among claims" can provide insight into "understanding the meaning of particular claim terms," and "the presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim." Id. at 1314-15 (citing Liebel-Flarsheim Co. v. Medrad, Inc., 358 F.3d 898, 910 (Fed. Cir. 2004)).

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Pursuant to 35 U.S.C. § 112(a), an inventor must use the patent specification to describe the claimed invention in "full, clear, concise, and exact terms." The patent specification therefore "is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term." Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996).

"[T]he specification may reveal a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess. In such cases, the inventor's lexicography governs." Phillips, 415 F.3d at 1316. "Even when the specification describes only a single embodiment, the claims of the patent will not be read restrictively unless the patentee has demonstrated a clear intention to limit the claim scope using words or expressions of manifest exclusion or restriction." Hill-Rom Servs., Inc. v. Stryker Corp., 755 F.3d 1367, 1372 (Fed. Cir. 2014) (quoting Liebel-Flarsheim, 358 F.3d at 906) (internal quotation marks omitted).

Nevertheless, a court may not import a limitation into the claims from the specification. Phillips, 415 F.3d at 1323. The Federal Circuit has "repeatedly warned" against limiting the claims

to the embodiments specifically described in the specification. Id. In other words, a court should not construe the patent claims as being limited to a single embodiment simply because the patent describes only one embodiment. Id. (citing Gemstar-TV Guide Int'l Inc. v. Int'l Trade Comm'n, 383 F.3d 1352, 1366 (Fed. Cir. 2004)).

A court "should also consider the patent's prosecution history, if it is in evidence." Markman, 52 F.3d at 980. The prosecution history, which is "intrinsic evidence," "consists of the complete record of the proceedings before the PTO [Patent and Trademark Office] and includes the prior art cited during the examination of the patent." Phillips, 415 F.3d at 1317. "[T]he prosecution history can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be." Id.

"The construction that stays true to the claim language and most naturally aligns with the patent's description of the invention will be, in the end, the correction construction." Renishaw PLC v. Marposs Societa' per Azionio, 158 F.3d 1243, 1250 (Fed. Cir. 1998). It follows that "a claim interpretation that

would exclude the inventor's device is rarely the correct interpretation." Osram GmbH v. Int'l Trade Comm'n, 505 F.3d 1351, 1358 (Fed. Cir. 2007) (quoting Modine Mfg. Co. v. U.S. Int'l Trade Comm'n, 75 F.3d 1545, 1550 (Fed. Cir. 1996)).

The Court begins its analysis by looking to the "actual words of the claim," Becton, Dickinson and Co. v. Tyco Healthcare Group, LP, 616 F.3d 1249, 1254 (Fed. Cir. 2010), as well as the context in which the disputed term appears. Phillips, 415 F.3d at 1314. Patent claims come in two general forms, independent and dependent. 35 U.S.C. § 112(c). Independent claims do not refer to another claim of the patent and are read separately to determine their scope. Inamin, Ltd. v. Magnetar Tech. Corp., 623 F.Supp.2d 1055, 1065 (C.D. Cal. 2009). Dependent claims, by contrast, refer to at least one other claim, include all of the limitations of the claim to which they refer, and specify a further limitation on that claim. 35 U.S.C. § 112(d); see also Monsanto Co. v. Syngenta Seeds, Inc., 503 F.3d 1352, 1357 (Fed. Cir. 2007).

With these legal principles in mind, the Court turns to the construction of the disputed terms among the asserted claims of the '526 patent.

III. DISCUSSION

As a preliminary matter, the parties agree that the term "1-[(4-methyl-quinazolin-2-yl)methyl]-3-methyl-7-(2-butyn-1-yl)-8-(3-(R)-aminopiperidin-1-yl)-xanthine"[4] means "linagliptin." (Dkt. No. 71 at 1). They also agree that "other references or chemical names for linagliptin, in the prior art for example, may be relied on for purposes of this case." Id. Boehringer contends that the disputed claim terms should be construed as limiting phrases. Id. at 1-3. Mylan argues these terms are non-limiting. Id. at 1-4.

A. DPP-4 Claim Term

1. The Claims

Independent claim 1 of the '526 patent reads:

> A method for treating and/or preventing type 2 diabetes mellitus in a patient having moderate or severe chronic renal impairment or end-stage renal disease comprising orally administering to the patient a DPP-4 inhibitor, which is 1-[(4-methyl-quinazolin-2-yl(methyl]-3-methyl-7-(2-butyn-1-yl)-8-(3-(R)-amino-piperidin-1-yl)-xanthine or a pharmaceutically acceptable salt thereof, wherein said DPP-4 inhibitor is administered in an oral dose of 5 mg per day to said patient, wherein metformin therapy for said patient is ineligible due to contraindication against metformin.

[4] This term is often spelled "1-[(4-methyl-quinazolin-2-yl)methyl]-3-methyl-7-(2-butyn-1-yl)-8-(3-(R)-amino-piperidin-1-yl)-xanthine" (See, e.g., Dkt. No. 72-9 at 29:44-45).

(Dkt. No. 72-9 at 29:40-49).

Dependent claim 2 reads:

> The method according to claim **1**, wherein said DPP-4 inhibitor is used for said patient in the same dose as for a patient with normal renal function.

Id. at 29:50-52.

Independent claim 8 reads:

> A method for treating type 2 diabetes mellitus in a patient with severe chronic renal impairment and for whom metformin therapy is ineligible due to contraindication against metformin, comprising orally administering to the patient a DPP-4 inhibitor which is 1-[(4-methyl-quinazolin-2-yl(methyl]-3-methyl-7-(2-butyn-1-yl)-8-(3-(R)-amino-piperidin-1-yl)-xanthine in a dose of 5 mg.

Id. at 30:17-24.

Independent claim 9 reads:

> A method for treating type 2 diabetes mellitus in a patient with severe chronic renal impairment and who is ineligible for metformin therapy due to contraindication against metformin, comprising orally administering to the patient a DPP-4 inhibitor which is 1-[(4-methyl-quinazolin-2-yl(methyl]-3-methyl-7-(2-butyn-1-yl)-8-(3-(R)-amino-piperidin-1-yl)-xanthine in a dose of 5 mg, wherein said DPP-4 inhibitor is used for said patient in the same dose as for a patient with normal renal function.

Id. at 30:25-33.

2. The Specification

The specification in the '526 patent provides in pertinent part:

> The present invention relates to certain DPP-4 inhibitors for treating and/or preventing metabolic diseases, particularly diabetes (especially type 2 diabetes mellitus) and conditions related thereto, in patients for whom normal metformin therapy is not appropriate (due to intolerability or contraindication against metformin), as well as to the use of these DPP-4 inhibitors in said treatment and/or prevention. Pharmaceutical compositions and combinations for treating and/or preventing metabolic diseases (particularly diabetes) in these patients comprising a DPP-4 inhibitor as defined herein optionally together with one or more other active substances are also contemplated.

(Dkt. No. 72-9 at 1:5-16).

> Another special embodiment of this invention refers to a DPP-4 inhibitor for use in the treatment and/or prevention of metabolic diseases (particularly type 2 diabetes mellitus) in patients for whom metformin therapy is inappropriate due to intolerability or contraindication against metformin (particularly in patients with renal disease, renal dysfunction or renal impairment), characterized in that said DPP-4 inhibitor is administered to said patients either in reduced dose levels or, advantageously, in the same dose levels as to patients with normal renal function, thus e.g. said DPP-4 inhibitor does not require downward dosing adjustment for impaired renal function.

Id. at 13:8-20.

3. Patent Prosecution History

Although the prosecution history of the '526 patent is not in evidence, Boehringer argues that the file history of the '877 patent is instructive because that patent is a continuation of the '526 patent and the two patents share a specification (Dkt. No. 72 at 13). According to the Federal Circuit, the patent prosecution history for a patent that is a continuation of a patent is relevant when interpreting claim terms in related patents. See Capital Mach. Co. v. Miller Veneers, Inc., 524 Fed. App'x 644, 649 (Fed. Cir. 2013) ("We have held that the prosecution history regarding a claim term is pertinent when interpreting the same term in both later-issued and earlier-issued patents in the same family.").

Like claims 2 and 9 of the '526 patent, claim 6 of the '877 patent includes the clause "wherein said 1-[(4-methyl-quinazolin-2-yl)methyl]-3-methyl-7-(2-butyn-1-yl)-8-(3-(R)-amino-piperidin-1-yl)-xanthine is used for said patient in the same dose as for a patient with normal renal function."(Dkt. No. 72-10 at 30:2-5). According to Boehringer, certain claims in its '877 patent application, including the claim that would become claim 6, were initially rejected as incomplete because they omitted essential

steps, with such omission amounting to a gap between the steps. (Dkt. No. 72 at 14-15; Dkt. No. 72-12 at 4). The Examiner noted that the omitted steps were "the administration time period for the method[] thus required to determine the limitation 'wherein no dose adjustment is required in patients with renal impairment.'" Id. at 15. The claims were also initially rejected as obvious over prior art primary references. Id.

Mylan contends that the changes Boehringer made during prosecution of the '877 patent were not material to patentability (Dkt. No. 79 at 10). As a key distinction, Mylan points to the fact that the original, rejected claims of the '877 patent did not require a linagliptin dose of 5 mg, although they contained both the "no dose adjustment" and "same dose" terms. Id. According to Mylan, this file history thus "strongly suggests" that it was the addition of the 5 mg claim term that persuaded the Examiner to allow the claims. Id. at 11. Mylan further asserts that a limitation, like the "same dose" claim term in the '877 patent, that does not appear in all claims is not material to patentability. Id.

Boehringer, however, asserts that it was through this initial rejection that the patent Examiner understood that the clause

directed to not adjusting dosage for a patient depending on renal function was a limitation in the method that was directed to concrete steps (Dkt. No. 72 at 15). Boehringer further contends that, during prosecution of the '877 patent, it clarified to the Examiner that this claim included two different limitations—(1) the 5 mg dose, and (2) no requirement for a dose adjustment. Id. at 15-16. Ultimately, as amended, and with Boehringer's explanation of its position, the claims of the '877 patent were allowed, including the claim with the "same dose" limitation in dispute here.

Based on this evidence from the prosecution history of the '877 patent, it is clear that Boehringer's argument that the claims required no adjustment of the 5 mg dose was expressly relied on by the Examiner "to define the claimed methods and distinguish them from the prior art." Allergan Sales, LLC, 935 F.3d at 1375-76. Therefore, the prosecution history of the '877 patent is relevant and instructive to the construction of the DPP-4 claim term at issue here.

4. Claim Differentiation

According to Boehringer, Mylan's construction would essentially read the disputed terms out of the claims. Generally, "a claim interpretation that would exclude the inventor's device is rarely the correct interpretation." Osram GmbH v. Int'l Trade

Comm'n, 505 F.3d 1351, 1358 (Fed. Cir. 2007) (additional citation omitted). But Mylan argues that this "general principle" of claim differentiation does not always apply (Dkt. No. 79 at 5-6).

Here, the claim differentiation doctrine bolsters Boehringer's argument but it is not the sole foundation supporting its interpretation of the DPP-4 claim term as limiting. Thus, even acknowledging that the claim differentiation doctrine is not a rigid rule, the authority and intrinsic evidence on which Boehringer relies support a finding that the DPP-4 claim term is limiting and should be given its plain meaning. The Court therefore rejects Mylan's claim construction, finding it would exclude Boehringer's invention.

B. "May" Claim Term

1. Claim Language

Independent claim 13 reads:

> A method of treating a type 2 diabetic patient with severe chronic renal impairment and for whom metformin therapy is ineligible due to contraindication against metformin comprising orally administering 5 mg of 1-[(4-methyl-quinazolin-2-yl(methyl]-3-methyl-7-(2-butyn-1-yl)-8-(3-(R)-amino-piperidin-1-yl)-xanthine to the patient, wherein the patient may be on insulin and/or sulfonylurea background medication.

Id. at 30:50-58.

2. The Specification

The specification of the '526 patent states, in pertinent part:

> In an embodiment of this invention, patients as described herein who are amenable to the treatment with a DPP-4 inhibitor as defined herein, optionally in (add-on or initial) combination with one or two conventional antihyperglycemic agents selected from sulphonylureas . . . and insulin or insulin analogues, may include, without being limited to, drug naïve as well as pre-treated diabetes patients

Dkt. No. 72-9 at 12:13-24.

> In a further embodiment of the present invention, it is provided a DPP-4 inhibitor as defined herein, optionally in combination with one or more conventional antihyperglycemic agents selected form sulphonylureas . . . and insulin and insulin analogues, for use in (first line) therapy of type 2 diabetes patients for whom metformin therapy is not appropriate (due to intolerance or contraindication against metformin).

Id. at 36-45.

> In a further embodiment of the present invention, it is provided a DPP-4 inhibitor as defined herein, optionally in combination with one or more conventional antihyperglycemic agents selected from sulphonylureas . . . and insulin and insulin analogues, for use in (second line or third line) therapy of type 2 diabetes patients for whom metformin therapy is not appropriate . . . and who are inadequately controlled on said conventional antihyperglycemic agent(s).

Id. at 46-56. The specification also includes a description of a clinical trial that studied the safety and efficacy of a DPP-4 inhibitor in patients with severe chronic renal impairment on insulin and/or sulfonylurea background medication:

> For other example, in a randomi[z]ed, double-blind, parallel group trial, the safety, efficacy and tolerability of a DPP-4 inhibitor according to the invention (e.g. 5 mg of BI 1356) is compared with placebo over a treatment period of 52 weeks in type 2 diabetic male and female patients with severe chronic renal impairment . . . including patients on insulin and/or sulfonylurea background medication.
>
> The safety and tolerability of the treatment is investigated by assessing patient's condition. The efficacy can be investigated by change from baseline in HbA1c after 12 weeks treatment, by change in fasting plasma glucose parameters, or by change in insulin and/or sulfonylurea dosage at 52 weeks compared to baseline and over time.

Id. at 28:66-29:12.

3. Analysis

Critically, the parties' dispute lies in their divergent interpretations of the word "may" in the "may" claim term: Boehringer interprets the "may" claim term to be permissive (i.e., that a patient being treated with sulfonylurea and/or insulin is eligible for treatment with linagliptin), while Mylan contends it is optional (and therefore, non-limiting), such that a patient treated with linagliptin could also take sulfonylurea and/or insulin, but is not required to do so. Based on the specification of the '526 patent, Boehringer's proposed construction of the "may" claim term as limiting is correct.

"Differences among claims can also be a useful guide in understanding the meaning of particular claim terms. For example,

the presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim." Phillips v. AWH Corp., 415 F.3d 1303, 1314-15 (Fed. Cir. 2005) (internal citations omitted). "Claims must be read in view of the 'entire specification.'" Allergan Sales, LLC v. Sandoz, Inc., 935 F.3d 1370, 1374 (Fed. Cir. 2019) (quoting Sinorgchem Co., Shandong v. Int'l Trade Comm'n, 511 F.3d 1132, 1145 (Fed. Cir. 2007) (emphasis in original)). "The specification is always highly relevant to the claim construction analysis and is, in fact, the single best guide to the meaning of a disputed term." Trs. of Columbia Univ. v. Symantec Corp., 811 F.3d 1359, 1363 (Fed. Cir. 2016) (emphasis in original).

Boehringer asserts that the "may" claim term is limiting because it identifies specific patient populations that could benefit from the treatment described in the '526 patent. See In re '318 Patent Infringement Litig., 578 F. Supp. 2d 711, 724-27 (D. Del. 2008), aff'd sub nom., 583 F.3d 1317 (Fed. Cir. 2009) (interpreting "[a] method of treating Alzheimer's disease and related dementias" as defining the scope of conditions to be treated); Glaxo Grp. Ltd. v. Teva Pharm. USA, Inc., No. C.A. 02-219, 2004 WL 1875017, at *10, *18-20 (D. Del. Aug. 20, 2004) (interpreting "a method of treatment for the relief of nausea and

vomiting" and "a method of treatment of nausea and vomiting" as defining the purpose of administering a treatment).

Boehringer further contends that other courts have construed "may" as a limiting term. See In re TR Labs Patent Litig., C.A. No. 09-3883 slip op. at 16, 18-19 (D.N.J. Aug. 7, 2014) (rejecting proposed position that "the plain meaning of the term 'may' connotes potentiality only."); Fifth Market, Inc. v. CME Group, Inc., C.A. No. 08-520 slip op. at 3 & n.13 (D. Del. Apr. 26, 2011).

Mylan, however, argues that a wherein clause is limiting only when it is "material to patentability." Allergan Sales v. Sandoz, Inc., 935 F.3d 1370, 1376 (Fed. Cir. 2019). In order for such a limitation to be material to patentability, the specification must make clear that the feature is critical to the invention or the limitation was relied on for patentability during prosecution. See, e.g., Dkt. No. 79 at 7, Allergan Sales LLC v. Sandoz, Inc., No. 2:17-CV-10129, 2018 WL 3675235 at *6 (D.N.J. July 13, 2018). Mylan contends that neither condition is present here.

Mylan also asserts that the use of the word "may" in the claim language "signals that the patient treated according to the method is optionally taking insulin and/or sulfonylurea background medication," and, thus, the disputed phrase is non-limiting (Dkt. No. 74 at 9). It also contends that Boehringer's interpretation of

the language in claim 13 is at odds with the other claims of the '526 patent because, as the drafter of the patent, Boehringer could have claimed combination treatment with insulin and sulfonylurea (Dkt. No. 79 at 13).

In the Court's view, the inclusion of the clinical trial information regarding this specific patient population, i.e., those on sulfonylurea and/or insulin background medication, supports Boehringer's position that the "may" claim term is limiting, not superfluous or optional. As so used, the "may" claim term signals that patients prescribed sulfonylurea and/or insulin can be prescribed a DPP-4 inhibitor (like linagliptin) in addition to these other medications, and the specification confirms that these patients will likely benefit from this combined treatment.

Taken in its entirety, this information demonstrates the critical nature of the "may" claim term. The overall aim of Boehringer's invention in the '526 patent is to treat patients for whom metformin is contraindicated in the same way as patients taking metformin. The patient population that cannot be prescribed metformin includes those with renal insufficiency, and may also include patients on other medications to treat type 2 diabetes. The "may" claim term in claim 13 confirms that patients who are treated with sulfonylurea and/or insulin are eligible to be prescribed a

DPP-4 inhibitor like linagliptin, not that patients who are treated with a DPP-4 inhibitor may also be taking sulfonylurea and/or insulin. Properly understood, the "may" claim term is focused on the specific patient populations that could benefit from treatment with linagliptin.

Therefore, after considering the entirety of the specification to determine the proper construction of the challenged claim term, the Court concludes that Boehringer's proposed construction of the "may" claim term, specifically, that it is to be construed in accordance with its plain language and is limiting, is correct.

IV. CONCLUSION

The Court **ADOPTS** Boehringer's proposed construction of the claim terms at issue and **CONSTRUES** the terms as follows:

1. ". . . wherein said DPP-4 inhibitor is used for said patient in the same dose as for a patient with normal renal function" consistent with its plain and ordinary meaning, that is, a limiting phrase.
2. ". . . wherein the patient may be on insulin and/or sulfonylurea background medication" consistent with its plain and ordinary meaning, that is, a limiting phrase.

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It is so **ORDERED.**

The Clerk **SHALL** transmit copies of this Order to counsel of record.

DATED: July 8, 2021

/s/ Irene M. Keeley
IRENE M. KEELEY
UNITED STATES DISTRICT JUDGE